DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 29, 2015

NOVA® Implants Ltd.
c/o Ms. Daniela Levy
Sterling Medical Registration
22817 Ventura Blvd
Woodland Hills, California 91364

Re: K150363
Trade/Device Name: NOVA® Dental Implants System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: May 13, 2015
Received: May 27, 2015

Dear Ms. Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control, and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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SECTION 4 - Indication for Use Statement

510(k) Number (if known):

K150363

Device Name:

NOVA® Dental Implants System

Indications for Use (*Describe*)

Indications for Use:

NOVA® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. NOVA® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Type of Use (Select one or both, as applicable)

☒Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use(21 CFR 801 Subpart

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON A SEPARATE PAGE IF NEEDED

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (*Signature*)

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SECTION 5 - 510(k) Summary (21 CFR 807.92)

510(k) Number K 150363

1	Submission Owner	NOVA® Implants Ltd. Dan Grimberg – CEO 5 Yoni Nethanyhu st., Or Yehuda ZIP 6037603 ISRAEL Phone : +972-77-3528166 Fax : +972-54-7528166		
2	Official Correspondent Contact Person	Sterling Medical Registration Daniela Levy - Regulatory Consultant 22817 Ventura blvd. Woodland Hills, CA 91364 Phone: 1-213-787-3027 Email: daniela@sterlingmedicalregistration.com		
3	Submission Date	June 21, 2015		
4	Device Trade Name	NOVA® Dental Implants System		
5	Regulation Description	Root-form Endosseous Dental Implants and Abutments		
6	Classification	Device Name	:	Endosseous dental implant
		Product Code	:	DZE, NHA
		Regulation No	:	872.3640
		Class	:	II
		Panel	:	Dental
7	Reason for the Premarket Notification Submission		:	New Device
8	Identification of Legally Marketed Predicate Devices		:	

NOVA® Dental Implants System is substantially equivalent to Alpha-Bio Tec K063364 (primary predicate); And referenced predicate devices: SGS International K133362; A.B.Dental Devices K051719, K112440, K132125; Paltop K112795; Nobel Biocare

K050705;

in terms of intended use, indication for use, technological characteristics, performance and user interface.

The predicate devices are a Class II medical device.

9 Device Description: :

NOVA® Dental Implants System consists of internal hex dental implants, cover screws and healing caps; abutments system and superstructures; impression copy system & surgical instruments.

Internal hex implants:-

PSI implants are provided in diameters: 3.3, 3.75, 4.2, 5 & 6 with lengths 8, 10, 11.5, 13, & 16 mm. (16 mm is not provided for 6 mm diameter).

PCI implants are provided in diameters: 3.3, 3.75, 4.2, 5 & 6 with lengths 8, 10, 11.5, 13, & 16 mm. (16 mm is not provided for 6 mm diameter).

NOVA Dental Abutments internal hex system provides:

Healing Caps:

HC Series - Narrow (3.75 mm) - Platform height 2,3,4,5,6,7

HC Series - Standard (4.7 mm) - Platform height 2,3,4,5,6,7

HCW Series - Wide (6.00 mm) - Platform height 3,4,5,6

PMI Series - Premium (3.75, 4.7, 6.0 mm) - Platform height 2,3,4,5,6,7

Straight Abutments (Long, straight, narrow, anatomic, curve):

ST Series: Length 8.5, 9.5, 11.5, 12.5 mm.

STA Series: With Shoulder profile height 1, Length 9 mm; profile height 2, Length 10; profile height 3, Length 11; profile height 4 Length 12.

STN: Narrow length 11 mm.

SLM Series: Anatomic Straight Abutment: profile height 1,2,3 length 9,10,11 mm.

SCM Series: Anatomic Straight Abutment: profile height 1,2,3 length 9,10,11 mm.

Angulated Abutments (standard, anatomic, curve):

Standard Angulated Abutment Length 7,9,11 Angulations 15º, 25º.

Anatomic Angulated Abutments Platform height 1,2,3,4 Angulations 15º, 25º.

Anatomic Angulated Curve Platform height 1,2,3, Angulations 15º, 25º .

Ball Attachments Platform height 1,2,3,4,5,6 and related components covers and caps.

Material:

NOVA® Dental Implants System and Dental Abutments System is made of Titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136.

10 Intended use / Indication for Use :

NOVA ® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. NOVA ® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

11 Performance Standards or Special Controls :

- ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry.
- ISO 5832-3:1996 Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy.
- ISO 14801 Second edition 2007-11-15 Dentistry-Implants-Dynamic fatigue test for endosseous dental implants.
- FDA guidance document: Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Guidance for Industry and FDA Staff.

12 Substantial Equivalence :

Substantial Equivalent Table	**Candidate No.1**	**PREDICATE DEVICE**
CHARACTERISTIC	**PCI Dental Implant**	**ATID Internal Hex Implants**
510k		K063364 (primary predicate)
Company Name	NOVA Implants Ltd.	Alpha-Bio Tec Ltd.
Indication for Use	NOVA® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. NOVA® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with	The Alpha-Bio Dental Implant System® is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. Two stage: ATID, DFI,SPI,SFB,ATIE OF, ITO, SPR One stage: ITO, SPR One stage and One Piece: ARRP,

	appropriate occlusal loading.	ARPB, ARRC 3mmd diameter are intended only for placement at the mandibular central and lateral incisors and maxillary and lateral incisors. Indicated also for denture stabilization using multiple implants One stage and One Piece for temporary use: ARR, ARB, ARS, ARSB permit immediate splint stability for crown, bridge and prosthesis, protect graft sites. The Alpha-Bio Dental Implant System® is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. DFI, SPI, ARRP, ARPB. The Alpha-Bio Dental Implant System® is indicated also for immediate loading on single tooth when good primary stability is achieved and with appropriate occlusal loading. SPI, SFB. All implants with diameter 3.3mmd should not use angled abutment.
Device Design	Threaded, root form endosseous implants	Threaded, root form endosseous implants
Classification	Class 2 872.3640 P.Code DZE	Class 2 872.3640 P.Code DZE
Material	GR-5 Titanium Ti-6Al-4V ELI	GR-5 Titanium Ti-6Al-4V ELI
Diameters mm	3.3, 3.75, 4.2, 5, 6	3.3, 3.75, 4.2, 5, 6
Lengths mm	8, 10, 11.5, 13, 16 [16 not for 6 mm]	8, 10, 11.5, 13, 16
Implant Body Contour	Straight	Straight
Anatomical Site	Oral Cavity	Oral Cavity
Principle of operation	Conventional procedure	Conventional procedure
Self tapping	✓	✓
Sterilization	Gamma Ray	Gamma Ray
Packaging	Double packaging	Double packaging
Bone preparation Procedure	Conventional drills	Conventional drills
Substantial Equivalent Table	**Candidate No.2**	**PREDICATE DEVICE**
CHARACTERISTIC	**PSI Dental Implant**	**SPI Internal Hex Implants**
510k		K063364 (primary predicate)
Company Name	NOVA Implants Ltd.	Alpha-Bio Tec Ltd.
Indication for Use	NOVA® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. NOVA®	The Alpha-Bio Dental Implant System® is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.

	Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	Two stage: ATID, DFI,SPI,SFB,ATIE OF, ITO, SPR One stage: ITO, SPR One stage and One Piece: ARRP, ARPB, ARRC 3mmd diameter are intended only for placement at the mandibular central and lateral incisors and maxillary and lateral incisors. Indicated also for denture stabilization using multiple implants One stage and One Piece for temporary use: ARR, ARB, ARS, ARSB permit immediate splint stability for crown, bridge and prosthesis, protect graft sites. The Alpha-Bio Dental Implant System® is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. DFI, SPI, ARRP, ARPB. The Alpha-Bio Dental Implant System® is indicated also for immediate loading on single tooth when good primary stability is achieved and with appropriate occlusal loading. SPI, SFB. All implants with diameter 3.3mmd should not use angled abutment.
Device Design	Threaded, root form endosseous implants	Threaded, root form endosseous implants
Classification	Class 2 872.3640 P.Code DZE	Class 2 872.3640 P.Code DZE
Material	GR-5 Titanium Ti-6Al-4V ELI	GR-5 Titanium Ti-6Al-4V ELI
Diameters mm	3.3, 3.75, 4.2, 5, 6	3.3, 3.75, 4.2, 5, 6
Lengths mm	8, 10, 11.5, 13, 16 [16 not for 6 mm]	8, 10, 11.5, 13, 16
Implant Body Contour	Tapered	Tapered
Anatomical Site	Oral Cavity	Oral Cavity
Principle of operation	Conventional procedure	Conventional procedure
Self tapping	✓	✓
Sterilization	Gamma Ray	Gamma Ray
Packaging	Double packaging	Double packaging
Bone preparation Procedure	Conventional drills	Conventional drills

	Product Code: NHA Regulation No. 872.3630		
	Candidate	*Reference Predicate Device*	*Reference Predicate Device*
	NOVA Implants ltd	***SGS International ltd***	***A.B.DENTAL DEVICES***
Product Name	Healing Abutments (PMI)	Healing Abutments (HN,HNN,HWN)	PON
K Number		K133362	K051719, K112440

Indication for Use	NOVA® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. NOVA® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	SGS® Dental Implants System is intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. SGS® Dental Implants System may be immediate loading when good primary stability is achieved and with appropriate occlusal loading. Two Stage Implants: P1, P7, P7N. One Stage: P7S, P9S. One Stage & One-Piece 3.0 mm diameter implants: P7S, P9S are intended for placement at the mandibular central and lateral incisors and maxillary and lateral incisors. Indicated also for denture stabilization using multiple implants. One stage & One-Piece 2.4 mm diameter implants for temporary use or long term use: P9S permit immediate splint stability and long term fixation of new or existing crown, bridge and prosthesis. PEEK Temporary Abutments are not to exceed 30 days.	The AB Dental Devices implants are intended *for* surgical' placement in the maxillary mandibular and/or arch to support crowns, bridges, or overdlentures in edlentulous or partially edentulous patients. 17 Integral implant, 15 Conical implant, P15 Temporary abutment, P12-T,L Temporary flat connection abutment, and P16 Straight adaptor are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
Dimensions	Narrow, Length: 2,3,4,5,6,7	Narrow, Length: 2,3,4	Narrow, Length: 3, 5, 7
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex	Internal Hex
	Candidate	*Reference Predicate Device*	*Reference Predicate Device*
	NOVA Implants ltd	***SGS International ltd***	***A.B.DENTAL DEVICES***
Product Name	Healing Abutments (HC, HCW)	Healing Abutments (H,HN, HW)	PO
K Number		K133362	K051719, K112440
Dimensions	Normal, Length:2,3,4,5,6,7 Narrow, Length: 2,3,4,5,6,7 Wide, Length: 3,4,5,6	Normal, Length:2,3,4,5,6 Narrow, Length:3,5 Wide, Length: 3,5	Normal, Length:2,3,4,5,6,7 Narrow, Length: 2,3,4,5,6,7 Wide, Length: 3,4,5,6
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex	Internal Hex
	Candidate	*Reference Predicate Device*	
	NOVA Implants ltd	***SGS International ltd***	
Product Name	Ball attachment BAT	Overdenture Ball attachment S3	

K Number		K133362	
Dimensions	Normal: Length:1,2,3,4,5,6,7	Normal: Length:1,2,3,4,5,6,7	
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	
Connection	Internal Hex, overdenture rest.	Internal Hex, overdenture rest.	
Related Components	Metal and silicon caps	Metal and silicon caps	
	Candidate	*Reference Predicate Device*	
	NOVA Implants ltd	***SGS International ltd***	
Product Name	Straight Titanium Abutment ST, STN	Straight Titanium Abutment S1N,S1WN, S1,S1N,S1W	
K Number		K133362	
Dimensions	Normal: Length: 8.5, 9.5, 11.5, 12.5 Narrow: Length: 9 (=with the external hex length its 11mm)	Narrow: Narrow, Wide - Length:9 Normal: Length: 5, 7, 9, 12, 15 Narrow: Length: 7, 9	
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	
Connection	Internal Hex	Internal Hex	
	Candidate	*Primary Predicate*	
	NOVA Implants ltd	***Alpha-Bio Tec***	
Product Name	Straight Titanium Abutment STA	Straight Titanium Abutment TLA1-4, TLASP	
K Number		K063364	
Dimensions	Normal: Profile Height 1, 2, 3,4 mm	Normal: Profile Height 1, 2, 3,4 mm	
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	
Connection	Internal Hex	Internal Hex	
	Candidate	*Reference Predicate Device*	*Reference Predicate Device*
	NOVA Implants ltd	***SGS International ltd***	**A.B. Dental Devices**
Product Name	Anatomic Straight Titanium Abutment SLM, SCM	Anatomic Straight Titanium Abutment S1A	Anatomic Straight Titanium Abutment P3S
K Number		K133362	K132125
Dimensions	Normal: Profile Height 1, 2, 3 mm	Normal: Profile Height 1, 2, 3 mm	Normal: Profile Height 1, 2, 3 mm
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex	Internal Hex
	Candidate	*Reference Predicate Device*	
	NOVA Implants ltd	***SGS International***	
Product Name	Angular Titanium Abutment ASM	Angular Titanium Abutment S2,S2L	
K Number		K133362	
Dimensions	Normal: Angle 15º, 25º- Length 7, 9, 11 mm	Normal: Angle 15º, 25º- Length 9, 11 mm	
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.

Connection	Internal Hex	Internal Hex	Internal Hex
	Candidate	*Reference Predicate Device*	*Reference Predicate Device*
	NOVA Implants ltd	***SGS International***	**Paltop**
Product Name	Anatomic Angular Titanium Abutment ANG	Anatomic Angular Titanium Abutment S2A , S2AN	Anatomic Angulated Abutments narrow/standard
K Number		K133362	K112795
Dimensions	Normal: Angle 15º, 25º- Profile 1,2, 3, 4 mm	Normal: Angle 15º, 25º- Profile 1,2, 3 mm	Normal: Angle 15º, 25º- Profile 1,2, 3 mm
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex	Internal Hex
	Candidate	*Reference Predicate Device*	*Reference Predicate Device*
	NOVA Implants ltd	***SGS International***	**Paltop**
Product Name	Anatomic Angular Titanium Abutment ANT	Anatomic Angular Titanium Abutment S2AN, S2AN	Anatomic Angulated Abutments narrow/standard
K Number		K133362	K112795
Dimensions	Normal: Angle 15º, 25º- Profile 1,2, 3 mm	Normal: Angle 15º, 25º- Profile 1,2, 3 mm	Normal: Angle 15º, 25º- Profile 1,2, 3 mm
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex	Internal Hex

Summary of Equivalence:

NOVA® Dental Implants System shares similarity to Alpha-Bio Tec K063364 (primary predicate); in terms of intended use, indication for use, technological characteristics, performance and user interface.

NOVA® Dental Abutments System shares similarity to Alpha-Bio Tec K063364 (primary predicate); And reference predicate devices: SGS International K133362; A.B.Dental Devices K051719, K112440, K132125; Paltop K112795; Nobel Biocare K050705; in terms of intended use, indication for use, technological characteristics, performance and user interface.

NOVA® Dental Implants System shares the same raw material as its predicated devices, the only difference whereas NOVA Dental Implants provides surface treatment of sand blast with acid etched in similar to Alpha Bio Tec K063364, and also anodized surface treatment, which is similar to Nobel Biocare K050705.

As demonstrated by the substantial equivalent table, the differences raise no new issues of safety or effectiveness, since NOVA® Dental Implants System and Dental Abutments System shares similarity to its predicate devices.

Clinical Testing - No clinical data is included in this submission.

Sterilization validation tests and Shelf life testing were carried out. Test results have demonstrated that the SAL of 10^{-6} was achieved and all testing requirements were met.

Mechanical Testing - NOVA® Implants Technologies has conducted Fatigue – Static & Cycling tests which comply with ISO 14801 Second edition 2007-11-15 Dentistry-Implants-Dynamic fatigue test for endosseous dental implants. The results of the fatigue load testing demonstrate that the subject devices are substantially equivalent to the predicate devices.

Biocompatibility test has been performed. Test results have demonstrated no evidence of causing cell lysis or toxicity and thus present equivalent performance as its predicate devices.

Risk management process was carried out with accordance to ISO 14971:2007.

The NOVA® Implants system shares the same intended use, raw material, design, technological characteristics, warnings, contraindications as its predicate devices and thus considered to be substantially equivalent to its predicate devices.

Conclusion:

As verified by bench testing, mechanical testing, risk assessment and substantial equivalence, NOVA® Dental Implant System shares similarity with its predicated devices by term of intended use, raw material and technical design. The fundamental scientific technology of the device is identical or very similar to the referenced predicate devices, therefore NOVA® Dental Implant System is considered to be substantially equivalent to its predicate devices.